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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,020	10/03/2005	Sanjay Suri	04-40419-US	9391

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Louis M Heidelberger
Reed Smith
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

EXAMINER	
YOUNG, SHAWQUIA	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,020	SURI ET AL.	
	Examiner	Art Unit	
	Shawquia Young	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 December 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/3/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are currently pending in the instant application.

I. *Priority*

The instant application is a 371 of PCT/IN02/00180, filed on September 3, 2002.

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on October 3, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

III. *Rejections*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystalline form VI atorvastatin calcium does not reasonably provide enablement for hydrates of the crystalline form. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered

when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a crystalline form VI atorvastatin calcium or hydrates thereof characterized by the X-ray powder diffraction pattern following 2θ values measured using a Shimadzu XRD-6000 with copper K radiation of λ1.5406°A and with a relative intensity of >15% 3.7365, 7.7200, 8.6985, 10.2185, 12.5933, 17.9103, 18.3600, 19.4031, 20.8200, 22.5122 and 25.5848.

The state of the prior art

It is the state of the prior art that approximately one-third of the pharmaceutically active substances are capable of forming crystalline hydrates. The water molecule, because of its small size, can easily fill structural voids and because of its multidirectional hydrogen bonding capability, is also ideal for linking a majority of drug

molecules into stable crystal structures. The mere presence of water in a system is not a sufficient reason to expect hydrate formation, because some compounds, though they are soluble in water, do not form hydrates. Predicting the formation of hydrates of a compound and the number of molecules of water incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of hyrates and hence generalizations cannot be made for a series of related compounds (Vippagunta, et al. 2001).

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what hydrates are being included in the elected invention. Applicants have not provided any data to characterize hydrates of crystalline Atorvastatin Calcium form VI. Also, Applicants have not shown how to prepare a hydrate form of crystalline atorvastatin calcium form VI.

The breadth of the claims

The breadth of the claims is a crystalline form VI atorvastatin calcium or hydrates thereof characterized by the X-ray powder diffraction pattern following 2θ values measured using a Shimadzu XRD-6000 with copper K radiation of λ1.5406°A and with a relative intensity of >15% 3.7365, 7.7200, 8.6985, 10.2185, 12.5933, 17.9103, 18.3600, 19.4031, 20.8200, 22.5122 and 25.5848.

The level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation.

The level of skill in the art is high without showing or guidance as to how to make the hydrates of the crystalline atorvastatin calcium form VI it would require undue experimentation to figure out the amount of water, drying temperatures and drying times that would provide all of the possible hydrates of the crystalline atorvastatin calcium form VI.

To overcome this objection, Applicant should submit an amendment deleting the term "hydrates".

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). *See Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mckenzie*, WO 97/03958. Applicants claim a crystalline form VI atorvastatin calcium or hydrates thereof characterized by the X-ray powder diffraction pattern following 2θ values measured using a Shimadzu XRD-6000 with copper K radiation of λ1.5406°A and with a relative intensity of >15% 3.7365, 7.7200, 8.6985, 10.2185, 12.5933, 17.9103, 18.3600, 19.4031, 20.8200, 22.5122 and 25.5848.

The Scope and Content of the Prior Art (MPEP §2141.01)

Mckenzie teaches a crystalline form III of atorvastatin calcium and hydrates, which are useful as a hypolipidemic and hypocholesterolemic agent.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Mckenzie* and the instant invention is that the applicants are claiming a crystalline form VI with a X-ray powder diffraction pattern following 2θ values measured using a Shimadzu XRD-6000 with copper K radiation of λ1.5406°A and with a relative intensity of >15% 3.7365, 7.7200, 8.6985, 10.2185, 12.5933, 17.9103, 18.3600, 19.4031, 20.8200, 22.5122 and 25.5848.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

Applicants have not shown any data (i.e., X-ray diffraction pattern) for the possible hydrates that are claimed in the invention. The hydrates that applicants are claiming should have its own X-ray diffraction pattern that is distinguishable from the crystalline form VI with a X-ray powder diffraction pattern following 2θ values measured using a Shimadzu XRD-6000 with copper K radiation of λ1.5406°A and with a relative intensity of >15% 3.7365, 7.7200, 8.6985, 10.2185, 12.5933, 17.9103, 18.3600, 19.4031, 20.8200, 22.5122 and 25.5848 and other hydrates that are already known in the prior art. It is not certain whether Applicants actually possess a hydrate of the crystalline form VI or the hydrates already known in the prior art reference *Mckenzie* absent data to characterize the claimed hydrates. Also, Applicants have not shown in the specification the reason that Applicants have prepared hydrates of crystalline form VI and the benefits when compared to the crystalline form VI and hydrates known in the prior art.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the phrase" as shown in Fig. 1" or "having the formula of Fig. 1" renders the claims indefinite, as Fig. 1 is not defined in the instant claims 8 and 9. The examiner must refer back to the disclosure to find the definition of Figure 1. A claim referring to the specification is improper except in rare

instances and fails to particularly point out the subject matter that applicant regards as the invention. Ex parte Fressola, 27 USPQ 2d 1608 (1993).

Claim 1 has a space after the term "15%" and it is unclear if essential information is missing. Appropriate correction is required.

V. Objections

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 10-17 and 20-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed and shall not serve as a basis for any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 10-17 and 20-22 have not been further treated on the merits.

Claim Objections

Claims 1, 3, 7 and 20 is objected to because of the following informalities: Claims 1, 3 and 7 are missing a period at the end of the claims. Claim 20 consists of

two sentences and a claim can only have one sentence. Claims 1 and 3 have the phrase "having characterized" but should read "characterized". Appropriate correction is required.

VI. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shawquia Young
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Joseph McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600